

## **REMARKS**

### ***I. Change of Ownership/Change of Attorney/Change of Correspondence Address***

Since the filing of the above-referenced application, the application has been assigned from its former owners, Zila Pharmaceuticals, Inc./Zila, Inc. to Blairex Laboratories, Inc. A copy of the Assignment is attached to this Response. Concurrently, the Assignment is being filed with the U.S. Patent Office Assignment Branch.

Enclosed with this Response is a copy of a Power of Attorney wherein the current Assignee, Blairex Laboratories, Inc. has granted a Power of Attorney to the undersigned to take over the prosecution of this application, and to correspond in all respects with the Office regarding this application.

The Office is respectfully requested to send all future correspondence to the undersigned at:

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### ***II. The Objections Under Section 112***

In the Official Action, the Examiner rejected Claim 9, under Section 112 as being indefinite. In particular, the Examiner believed it unclear as to whether the hydrophobic group in part (2) of Claim 9 was covalently or non-covalently attached to the water soluble polymer. Additionally, the Examiner believed it was unclear as to whether the hydrophobic group in part

(2) is a limitation of the water soluble polymer because of the future tense, and believed it unclear as to whether the hydrophobic group being used to modify the water soluble polymer is the same as the hydrophobic group in part (3). Further, the Examiner believed it to be unclear as to where the hydrophobic groups in part (2) and (3) were.

With this Amendment, the Applicant has amended Claim 9 to overcome these objections. In particular, the Examiner should note that Claim 9 now includes a recitation that the water soluble polymer is capable of attaching to a hydrophobic group through covalent bonding, to address the first and second lack of clarity issues raised by the Examiner.

Part (3) of Claim 9 has been amended to include the term “compound containing”, to address the Examiner’s fourth issue of lack of clarity. Additionally, parts (2) and (3) have been amended to address the third issue of lack of clarity raised by the Examiner.

For the reasons set forth above, the Applicant submits that the claim, as amended, overcomes the Examiner’s rejections based on Section 112.

### ***III. The Substantive Rejections***

The Examiner rejected Claim 9 as either being anticipated, or the alternative, as being obvious over Katada et al., U.S. Patent No. 5,080,889. Additionally, the Examiner rejected Claim 9 under Section 103 as being unpatentable over Mueller et al., U.S. Patent No. 4,826,677.

#### ***A. Katada, U.S. Patent No. 5,080,889***

Katada relates to dyglycerins and cosmetic compositions. Although the Examiner is correct that Katada does disclose using ethanol and carboxymethylcellulose, Katada does not

disclose or suggest using the water soluble polymer selected from the Applicant's claimed Group, and then modifying the water solubility of the polymer by attaching the hydrophobic group of the compound containing the hydrophobic group to the water soluble polymer to produce a water insoluble interaction product. It is also noteworthy that Katada's compounds are used exclusively in connection with the production of compositions designed to be used externally, on the skin or hair. Nothing in Katada discloses or suggests that the composition disclosed therein would be capable of forming a film that adheres to a body tissue, that is capable of being used on a mucosal surface, such as an intra-oral surface, such as the Applicant's composition.

*B. Mueller, U.S. Patent 4,826,677*

Mueller relates to a pharmaceutical material for the treatment of psoriasis.

Although Mueller does teach the formation of a film-forming composition, the composition taught by Mueller is very different than that claimed by the Applicant. In particular, nothing in Mueller discloses or suggests modifying the water solubility of the polymer in a liquid composition by attaching the hydrophobic group of the compound containing the hydrophobic group to the water soluble polymer to produce a water insoluble interaction product.

Additionally, it should be noted that Mueller, like Katada, discloses a product to be used almost exclusively on an external body surface. As such, nothing in Mueller discloses or suggests that his composition could be used or be capable of forming an appropriate film on a mucosal or intra-oral surface. By contrast, the fact that Mueller discloses that his film is preferably water permeable would likely suggest that a suitable film would not be formed in a

highly aqueous environment, such as a mucosal tissue.

***IV. Conclusion***

For the foregoing reasons, the Applicant submits that his claims, as amended, patentably distinguish the Applicant's invention from the art of record. Re-examination and re-consideration, culminating in the allowance of all the claim, is respectfully requested.

It is respectfully requested that the Examiner so find and issue a Notice of Allowance in due course.

***V. Request for Appropriate Extension of Time***

If necessary, Applicant requests that this Response be considered a request for an extension of time for a time appropriate for the response to be timely filed. Applicant requests that any required fees needed beyond those submitted with this Response be charged to the account of E. Victor Indiano, Deposit Account Number 50-1590.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'E. Victor Indiano', is written over a horizontal line.

E. Victor Indiano  
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Encl. Copy of Assignment  
Power of Attorney

cc: Mr. Tony Moravec

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